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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/656,364	09/06/2000	Alice C. Martino	6107.N CN2	3730

7590

04/09/2003

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EXAMINER

SHARAREH, SHAHNAM J

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 04/09/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/656,364

Applicant(s)

MARTINO ET AL.

Examiner

Shahnam Sharareh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24, 26, 30 and 33-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24, 26, 30 and 33-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 15.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 16, 2003 has been entered.

Claims 1-24, 26, 30, 33-38 are pending. Any rejection previously on record that is not addressed in this Office Action is considered obviated in view of the amendments and the Declaration filed under 37 CFR 1.132, Paper No. 14.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 35-37 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 35 recites the limitation "microcrystalline cellulose" in line 18 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claims 1-12, 21-24, 26, 30, 33-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Elger et al US Patent 4,844,907.

The instant claims are directed to tablets comprising a rapidly precipitating drug wherein the rapidly precipitating drug is a soluble salt form of a poorly soluble free base or free acid or an anhydrous form of a poorly soluble free base or free acid that is prone to super saturation when introduced in water and at least a binder in amount of 2 to about 25% wt, or at least a superdisintegrant in an amount from about 6 to about 40% wt. Examiner draws applicant's attention to the recitation of Markush language in independent claims 1, 35, wherein the claimed composition can contain either a binder or a superdisintegrant.

Applicant is also informed that the pending claims are drafted in the form of product by process. Accordingly, in product claims that are limited by and defined by a

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process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product - by - process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985). Thus, the process steps are not limiting to the products instantly claimed so long as the product of the prior art is the same as those instantly claimed.

Elger meets all limitations of the instant claims. Elger discloses a rapidly precipitating drug with in the scope of the instant claims such as dihydrocodine tartrate, Ibuprofen, pentazocine hydrochloride, hydromorphone hydrochloride, hydrocodone tartrate (see col 2, lines 4-29; col 6, lines 1-67; col 10, lines 1-67). The amounts of said drugs are in the same range as instantly claimed. Elger also discloses a binder such as microcrystalline cellulose or starch, PVP (see col 4, lines 1-3; all examples). Elger also discloses the use of instantly claimed disintegrants such as sodium starch glycollate, croscarmellose or hydroxypropyl cellulose (see col 4, lines 5-10; all examples). Elger uses such ingredients respectively in ranges of about 5-30% and 5-25% in his comparative and inventive examples (see col 5, line 55-col10, line 40).

3. Claims 1-24, 26, 30, 33-37 are rejected under 35 U.S.C. 102(e) as being anticipated by Makooi-Morehead et al US Patent 6,238,695.

Makooi-Morehead discloses tablets comprising a highly insoluble drug such as efavirnez in amounts of about 22-50%, a superdisintegrant such as sodium starch glycolate in amount of about 13-30%, a binder such as (microcrystalline cellulose in

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amounts of about 20%, lactose in amounts of about 7-22%, talc in amounts of 1.75%, a lubricant such as magnesium stearate in amount of about 1-2% (see entire col 6-8).

Efavirnez is considered to meet the limitation of instant drugs because it is in anhydrous form (free of water) and is considered highly insoluble (col 1, line 65-col 2, line 3), thus, inherently meeting the functional limitations of the instantly claimed drugs. Therefore, Makooi-Morehead is an anticipatory reference.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

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not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-24, 26, 30, 33-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Elger or Clorpress® Package Insert in view of Makooi-Morehead US Patent 6,238,695.

Elger's teachings are discussed above. Elger lacks the specific teachings for using lactose and colloidal silicone dioxide in a tablet formulation.

Clorpress is also used to show the conventional nature of using a pharmaceutically active agent such as clonidine hydrochloride (within the scope of instant agents), colloidal silicon dioxide, croscarmellose, magnesium stearate, and microcrystalline cellulose in a tablet formulation. Clorpress lacks the use of lactose, silicone dioxide and the specific amounts instantly claimed for each ingredient.

Makooi-Morehead shows that the use of lactose; a flow agent such as colloidal silicon dioxide; a superdisintegrants such as croscarmellose and sodium glycolate, and a binder such as microcrystalline are well established in the art. Makooi teaches that such combination of ingredients improves the rate of dissolution and thus the extent of absorption in the GI-track. (col 2, lines 3-7). Accordingly utilizing them and further optimizing their concentrations for desired rate and extent of absorption is well within purview of an ordinary artisan (see col 5, line 40-col 6, line16; col 7, line15-col 8, line33). Makooi-Morehead fails to specifically characterize efavirnez as a rapidly precipitating drug within the scope of instant claims.

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Nevertheless, it would have been obvious to one of ordinary skill in the art at the time of invention to employ lactose and colloidal silicone dioxide in suitable amounts within the compositions of Elger, or the formulation of Clorpress, and further optimize all concentrations in a tablet dosage form, because as taught by Makooi-Morehead, the ordinary artisan would have had a reasonable expectation of success in improving the rate of dissolution of a insoluble drug and subsequently its extent of absorption in GI track.


Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh, PharmD whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 703-308-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

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April 2, 2003


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